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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,088	12/06/2004	Jianming Chen	6480P0010US	1147

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EXAMINER
KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
01/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,088	CHEN ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7 and 9-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 12-3-08 is acknowledged.

Claims included in the prosecution are 7, 9-14.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The examiner suggests reciting specific steps in claim 12 and avoid expressions such as 'can also be obtained from the lipid solution'. This rejection is maintained since applicant has not addressed this issue.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 7 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al US 2003/0118616 in view of Garrity (6,045,821).

Lee et al disclose liposomal formulations containing lecithin, 0011, 0023, Retinol (Vitamin A), 1 % and sorbitol (2 %) (abstract and Table 4 on page 5). What is lacking in Lee et al is the teaching of the use of sodium chloride.

Garrity while disclosing liposomal formulations teaches that sorbitol, mannitol and sodium chloride are cryoprotectants which aid the lyophilization and reconstitution processes (abstract, col. 12, lines 29-32; col. 9, lines 14-30).

The use of sodium chloride instead of sorbitol in the liposomes of Lee et al with a reasonable expectation of success would have been obvious to one of ordinary skill in the art since Garrity teaches the equivalency between sorbitol and sodium chloride as cryoprotectants.

5. Claims 7 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller (6,610,322) by itself or in view of Garrity (6,045,821).

Keller discloses liposomal preparations containing tretinoin (Example 7). Keller further suggests that the liposomes can be lyophilized in the presence of appropriate cryoprotectant (col. 7, lines 30-35). Although Keller does not disclose sodium chloride and its amounts, it would have been obvious to use sodium chloride in appropriate amounts with a reasonable expectation of success since sodium chloride is a known cryoprotectant a shown by Garrity. The use of lecithin would have been obvious to one of ordinary skill in the art since Garrity also shows that it is commonly used phospholipid in liposomal preparations (examples).

6. Claims 7 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Cole (6,544,531) or Meybeck (5,034,228) in view of Clerc (5,939,096) and Garrity (6,045,821).

Cole discloses liposomes containing retinol. The compositions also contain Brij (Example 1).

Meybeck similarly discloses liposomal compositions containing tretinoin. Meybeck further teaches lyophilizing the composition (preliposomes). The composition further contains a buffer and sodium chloride (Examples 3-7). Sodium chloride however, is used in Meybeck to suspend the liposomes.

What are lacking in Cole and Meybeck are the teachings of the inclusion of cryoprotectant in the preparation of liposomes. Cole further lacks lyophilization of the composition.

Garrity as discussed above teaches that the liposomes can be stored in a lyophilized form and that sodium chloride acts as a cryopreservative.

It would have been obvious to use sodium chloride in appropriate amounts in the compositions of Cole or Meybeck since sodium chloride is a known cryoprotectant as shown by Garrity.

7. Claims 7 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al US 2003/0118616 or Keller (6,610,322) or Cole (6,544,531) or Meybeck (5,034,228) or Mehta (5,811,119) in view of Schneider (4,229,360).

The teachings of Lee, Keller, Cole and Meybeck have been discussed above.

Mehta teaches liposomal formulations containing retinoids. The liposomes are prepared in a lyophilized form (example 1).

What is lacking in these references is the teaching of the use of polyvinyl pyrrolidone.

Schneider teaches that for prolonged storage of the liposomes, a hydrophilic compound such as polyvinyl pyrrolidone (1:1) must be included in the composition (abstract, col. 1, line 42 through col. 2, line 17 and examples).

The inclusion of polyvinyl pyrrolidone in the compositions of Lee, Keller, Cole, Meybeck and Mehta would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since Schneider teaches that polyvinyl pyrrolidone helps liposomes during prolonged storage.

The reference of Kato (5,945,121) which teaches liposomal formulations containing vitamin A is cited as interest.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore /
Primary Examiner, Art Unit 1612

GSK